

APPENDIX 3

Literature Review:

Methodology:

No x-rays have been submitted either for my personal review or to any other independent review or panel of reviewers to the best of my knowledge. I have performed a review of the asbestos literature emphasizing studies performed by authors who have either been retained as experts or are commonly recognized as authoritative by plaintiff counsel in asbestos litigation. I have also included studies performed at the request of unions. I have attempted to identify studies which are performed on individuals with high levels of asbestos exposure, low levels of asbestos exposure and various durations of exposure. Studies are chosen to represent various settings in which asbestos is the predominant fibrogenic dust including shipyards, railroads, construction trades, insulators, petrochemical industry, household and others. Because asbestos causes a spectrum of disease affecting both the pleura and the pulmonary parenchyma, it is possible to define the distribution of nonmalignant disease among the various cohorts which have been reported. The interpretation submitted by the plaintiffs "B" readers are then compared to the findings of the peer review literature. In addition, this methodology allows comparison of "B" readers with each other.

1) Dr. Irvin J. Selikoff¹ - household exposure

<u>Number</u>	<u>Exposure</u>	<u>Pleural only</u>	<u>Parenchymal</u>	<u>Pleural</u>	<u>Ratio Pl/Parenchymal</u>
		<u>& Parenchymal</u>			
326	326	52	35	27	1.5:1
	Household				
	Members of				
	Amosite				
	Asbestos workers				

Comment: Dr. Selikoff cited work of Anderson, Lillis & Selikoff² which studied effects of asbestos on household contacts of amosite asbestos workers

2) Albert Miller, Ruth Lilis, Selikoff et al³ - insulators

<u>Number</u>	<u>Exposure</u>	<u>Pleural only</u>	<u>Parenchymal only</u>	<u>Pleural & parenchymal</u>	<u>Ratio Pl/P</u>
2611	long term insulators	633 (24%)	301 (11.5%)	1,256 (48%)	2.1:1

Comment: Represents very heavy exposure in long term asbestos insulators (Table 5, pg 178).

Any parenchymal involvement (parench. or pleural plus parenchymal = 54.5%)

Any pleural involvement (pleural or pleural and parenchymal) = 72.5%

3) Albert Miller, Ruth Lilis et al⁴ - sheet metal workersNumber Exposure

1245 Sheet metal workers with at least 20 yrs
in the trade were compared with insulators

Comment: pleural present = 468 (Table 10)

Total interstitial (1/0+) = 226 (Table 11)

excerpts from Miller⁴

Ratio Pl/P 2:1

Total with pleural fibrosis = 36%

Total with pulmonary fibrosis = 17.5%

All workers had at least 20 years in the trade. The abstract stated that "consistent with their less continuous and less extensive exposure to asbestos, metals workers had a far less frequent radiographic asbestosis" (profusion score greater than or equal to 1/0, 17.5% vs 59.5% for insulators). They also experienced less pleural fibrosis 36% vs 75% and less frequent restrictive impairment 23% vs 33%.

Summary: Sheet metal workers had only 30% the incidence of asbestosis and 50% the incidence of pleural disease of insulators.

4) National Sheet Metal Worker Asbestos Screening Program, Laura S. Welch et al ⁶

<u>Number</u>	<u>Exposure</u>	<u>Pleural only</u>	<u>Parenchymal (1/0+)</u>	<u>Both</u>
9,605	sheet metal workers employed in the trade at least <u>20 yrs</u> before examination Median age 57 Average 32.8 yrs in the industry average 35 yrs since first became sheet metal worker 75% smoked	18.8%	6.6%	5.7%
		Ratio P/P 2.84:1		
2,552	sheet metal workers <u>40 or more years</u> since entering sheet metal trade	24.2%	7.7%	9.6%

Comment - Overall prevalence of asbestos related abnormalities was 31.1%, 18.8% had pleural abnormalities alone, 6.6% had parenchymal abnormalities alone (1/0 or higher) and 5.7% had both. Of those with 40 years or more from entering the trade, 41.5% had x-ray findings of asbestos related disease with 24.2% being pleural disease alone, 7.7% parenchymal alone and 9.6% both pleural and parenchymal. All workers had at least 20 or more years in the trade.

less than 1% of cases were 2/1 or higher with the majority being category 1/0 or 1/1

The difference between Welch study and Miller of sheet metal workers may reflect that Welch represented lower exposure as Miller's study was only conducted in 1986-7. Also only one B reader was used in the Miller study vs the large panel in Welch. The Welch study was far larger (9605 vs 1245).

Among the B readers and A readers participating in this study include the following who are recognized as having been retained as experts by plaintiffs or whose literature has been cited by plaintiffs experts - Mark Cohen MD - Yale Univ, Harold Frukim MD - Emory Univ, Arthur Frank MD - Univ of Kentucky Medical Center Lexington, Gary Friedman MD - Texas Lung Institute Houston, Edward Holstein MD, James Merchant MD - University of Iowa Iowa City, Chris Oliver MD- Massachusettes General Hospital Boston, Linda Rosenstock MD - University of Washington Seattle, David Schwartz MD - Univ of Iowa. There may be others represented as well with whom I am not familiar. The study was sponsored by the financial support of the Sheet Metal Workers International Assn and the Sheet Metal Occupational Health Institute

5) Irving Selikoff⁵ - shipyard/dockyard workers

<u>Exposure</u>	<u>Pleural</u>	<u>Parenchymal</u>	<u>Ratio P/P</u>
Continuous/Heavy Laggers, sprayers, masons asbestos storemen	46%	7%	6.5:1
Intermittent Electric fitter, riveter burner, welder, shipfitter	8%	0%	
Intermittent shipwright	5%	0%	
Insignificant exposure	3%	0%	

Comment: From Sheers - British Medical Journal

Dr. Selikoff comments on these findings noting "the preponderance of pleural changes in this group is illustrative of the changing type of response now being seen in those with low levels but long periods of exposure. Three years later McKenzie reported a similar prevalence had been found at other naval dock yards"^{5A}

Dr. Selikoff further identifies this decline in severity of parenchymal disease in his 1978 publication⁷ (page 215) "as mentioned above a large portion of the cases that make up these statistics had their origin in past years when dust levels were generally much higher than they are today. We would expect that with improvement in working conditions, the number of new cases would be less and that a longer time would elapse before the disease reaches the stage of being radiologically detectable. In view of what was said above, we would expect this to be true particularly for parenchymal fibrosis, to be less apparent than pleural calcifications". In 1966 Smither offered evidence supporting one of these expectations (footnote 7 Smither WJ Asbestos Asbestosis and Mesothelioma of the Pleura proceedings Royal Society of Medicine 59, 57 1966) "One means of observing the change in the incidence of asbestosis is to declare the average length of asbestos exposure before the onset of certifiable disability. In the early 1930s Hunter (1955) cases average 7 years. In the 1940s Wyers' (1949) cases average 10.4 years. In the 1950s, the cases reported had an average of 14.5 years. My series of cases all from the same factory and certified since 1960 shows an average exposure of 17.5 years". These would have represented exposures occurring in the 1930s/1940s and 1950s and were published in 1966 approximately 7 years prior to the discontinuation of asbestos insulation usage and add one more piece of information concerning the expected decline in incidence of parenchymal asbestosis.

6) Oliver, Christine et al - School custodians⁷

<u>Number</u>	<u>Exposure</u>	<u>Pleural plaque</u>	<u>Parenchymal 1/0</u>	<u>Ratio P/P</u>
120	public school custodian	40 (33%)	3 (2.5%)	13:1

Comment: All three cases of 1/0 interstitial fibrosis had reported outside exposure to asbestos beyond their employment as a custodian. This issue becomes important as it may relate to low dose exposures.

7) Dr. David Schwartz - varied trades, heavy exposure

<u>Number</u>	<u>Exposure</u>	<u>Pleural</u>	<u>Parenchymal 1/0 (+)</u>	<u>Both</u>
117	1 yr or more exposure +20 or more yrs of latency on <u>high</u> <u>exposure</u> industries. Mean duration of exposure 32 yrs Mean time since first exposure 38 yrs	46 (40%)	19 (17%)	19 (17%)
		Ratio P/P 2.4:1		

Comment: "Our results demonstrate that pleural fibrosis and in particular diffuse pleural thickening is independently associated with persistently lower measures of lung volume. This supports the observations of previous investigators and further demonstrates the physiologic importance of these radiographic abnormalities. Asbestos induced pleural fibrosis has been independently associated with excess dyspnea and lower lung volumes. The results of this study indicate that asbestos induced pleural fibrosis has long term consequences in relationship to the persistently lower measures of lung volume. In contrast to asbestosis on the chest radiograph and interstitial changes on HRCT were not significantly related to lower measures of TLC during the period of observation. This suggests that pleural fibrosis rather than asbestosis may be particularly important in identifying those workers who are more likely to have persistently lower measures of lung volume" (page 1248).

This article is important as are numerous of the other articles in pointing out the importance of identifying pleural fibrosis and its contribution to impairment.

8) NIOSH Evaluation of Exxon Refinery Bayway, NJ - stratified by occupation and length of employment

Comment: This health hazard evaluation was performed at the request of the workers and their union. Since 1972 only nonasbestos insulation materials had been installed in the refinery and chemical plant. The report states "asbestos exposure in refineries are generally thought to be lower than that experienced by insulators, asbestos miners or asbestos product workers. Therefore the spectrum of health effects is expected to shift so that pleural abnormalities predominate". The union was concerned about the prevalence and consequence of these pleural abnormalities among members of the work force who had little, direct or extensive exposure to asbestos.

Analysis was broken down by degree of exposure as well as length of exposure. Representative figures are as follows:

Table 8-1

<u>Number</u>	<u>Exposure</u>	<u>Pleural</u>	<u>Parenchymal</u>	<u>Both</u>	<u>Either</u>
90	high level Insulators, pipefitters boilermakers	33 (37%)	8 (9%)	(7%)	35 (39%)

Table 8-2

298	masons, painters carpenters, welders laborer pre 1966 rigger, heavy equipment operator	69 (23%)	30(10%)	(5%)	88(30%)
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Table 8-3

82	lesser exposure storehouse worker, tank cleaner, security	21 (25%)	12(14%)	(4%)	27(32%)
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Table 8-4

72	construction noninsulator nonboilermaker nonpipefitter 21-30 yrs	14 (19%)	5 (6%)	(4-5%)	18 (25%)
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Table 8-5

143	employed 31-40 yrs Construction workers	36 (25%)	15 (10%)	(5%)	44(30%)
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Group B

Table 8-6

16	employed 40+ yrs Construction workers	5 (31%)	3 (23%)	(5%)
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Table 8-7

44	1-10 yrs exposure Refinery workers	13 (29%)	8(18%)	(4%)	17(38%)
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Comment: The percentage for "both" is estimated from the figures given as the authors only included "either" for these tables. It is also drawn from Table 8-8 where current employees had a 4% occurrence of both, retirees had 5% occurrence of both and the total for the group was 5%. Such numbers are consistent with findings of other authors and also are consistent with calculations which I made using pleural parenchymal and either. I believe that the accurate number for both would be 5% (+/-) 1% with higher estimates given for high level and long term exposure and the 4% estimates given for those with lesser exposure.

Table 8-8 Based on employment status

		<u>Pleural</u>	<u>Parenchymal</u>	<u>Both</u>	<u>Either</u>	<u>Ratio</u>
109	current employees	35 (32%)	7(6%)	5 (4%)	37(34%)	5:1
392	retired employees	91 (23%)	48(12%)	20 (5%)	119(31%)	1.9:1
501	total	126 (25%)	55(11%)	25(5%)	156(31%)	2.3:1

9) Dr. Victor Roggli and Donald Greenberg - Correlation of Asbestos Fiber Level and Pathologic Findings of Pleural Plaque vs Pulmonary Fibrosis

Roggli¹⁰ & 10A confirms that pleural plaques average 1450 asbestos bodies per gram by light microscopy vs 37,800 in asbestosis and 26,000 uncoated fibers by scanning electron microscopy vs 330,000 in asbestosis. There is pathologic evidence as to why pleural plaque should be a more common finding than is interstitial fibrosis (asbestosis). As levels of exposure diminish subsequent to 1973, there is no rational basis for an increase in the incidence of pulmonary asbestosis especially in the absence of an accompanying increase in pleural disease.

10) Rosenstock, Linda - Plumbing and pipefitters - smoking status¹¹

<u>Number</u>	<u>Exposure</u>	<u>Pleural</u>	<u>Parenchymal</u>	<u>Both</u>	<u>Ratio</u>
681	plumbing & pipefitting	118(17%)	50 (7%)	82 (12%)	2.36:1

Comment: It should be noted that 62% of those with parenchymal fibrosis also had pleural abnormalities. 91% of those with parenchymal abnormalities had 1/1 or 1/0. Mean duration in the plumbing and pipefitting trade 17.1 years.

11) Merchant, James - Railroad workers¹²

<u>Number</u>	<u>Exposure</u>	<u>Pleural</u>	<u>Parenchymal</u>	<u>Both</u>	<u>Ratio</u>
266	Current and former railroad workers 75% over age 60	49(23%)	3(1.5%)	3 (1.5%)	16:1

- 12) Hillerdal et al¹⁴ published on the broad spectrum of asbestos related disease. His opinions reflect the findings of all the above studies **"in most investigations pleural plaques are the most common radiological finding in persons exposed to asbestos"** (page 96).
- 13) Montserrat Garcia Closas et al at the Harvard School of Public Health¹⁵ studied construction carpenters at the request of the union. In that study he noted **"pleural plaque was the asbestos related disease most prevalent"**. 16.8% had pleural fibrosis while only 6.8% had interstitial markings consistent with fibrosis.
- 14) Hillerdal et al reported in the Journal CHEST in 1994 on the incidence of pleural plaque stating "since they can occur even with relatively low exposure pleural plaques are nowadays by far the most common lesion seen in persons exposed to asbestos".
- 15) Dr. Irving Selikoff¹³ studied the influence of smoking on pleural fibrosis vs pulmonary fibrosis. A study of 1,117 insulation workers demonstrated the pleural changes to be more common than pulmonary fibrosis regardless of smoking history (page 469).

16) Lilis Chemical Plant & Oil Refinery Maintenance Workers -
 "Chemical Plant Maintenance Workers", page 797¹⁷

<u>Number</u>	<u>Pleural</u>	<u>Parenchymal</u>	<u>Both</u>	<u>Ratio</u>
185	14%	10%	14%	1.4:1

"Chemical Plant Workers with greater than 20 years"

<u>Pleural</u>	<u>Parenchymal</u>	<u>Ratio</u>
22%	10%	2.2:1

"Oil Refinery Workers", page 802

<u>Number</u>	<u>Pleural</u>	<u>Parenchymal</u>	<u>Both</u>	<u>Ratio</u>
135	17%	14.8%	8.2%	1.2:1

Comment: It should be noted that the 1972 ILO schema (not 1980) was utilized and definition for restriction was based only on FVC of less than 80% and thus it is possible that some of these individuals may have also been obstructed. Despite this fact, it was stated "in chemical plant maintenance workers, pulmonary function tests Table 13 indicated a relatively low prevalence of restrictive dysfunction (5% of cases), probably related to the small number of cases with advanced parenchymal fibrosis". In oil refinery workers, restrictive defect (FVC less than 80% of predicted) was found in 14% of cases (page 803). It is not known whether combined obstructive/restrictive defect would have been included in this definition as it only relates to the FVC of less than 80%. Lilis reaches the following conclusions on page 806, "the higher prevalence of radiological pleural abnormalities (pleural fibrosis and/or calcification) than of parenchymal small irregular opacities (interstitial pulmonary fibrosis), the fact that parenchymal abnormalities were not very advanced (in only a small proportion of cases exceeding 2/1), and the paucity of clinical abnormalities all indicate that the risk for disabling asbestosis is less with this type of asbestos exposure." The occupations were described as having "no direct handling of asbestos" (page 805) and surprisingly included such trades as pipefitter, boilermaker, millwright, sheet metal mechanic, stock man, carpenter, crane operator, electrician, painter, still operator, welder and others. This speaks to the incidence of impairment.

17) Edge Shipyard¹⁸ - Dr. Selikoff cites Edge who studied (page 219) 80,000 employees in shipbuilding in England and noted that 6% had pleural disease and only 0.5% had pulmonary fibrosis.

<u>Number</u>	<u>Exposure</u>	<u>Pleural</u>	<u>Pulmonary</u>	<u>Ratio</u>
80,000	shipyard	6%	0.5%	12:1

GLOSSARY

Asbestosis	scarring of the inside of the lung caused by asbestos
ATS	American Thoracic Society
"B" reader	a doctor who has learned to read x-rays according to the ILO system and successfully passed an examination given by NIOSH
BHT	Breath hold time (9-11 seconds is required by ATS)
DLCO	see diffusion capacity
Diffusion Capacity (DLCO)	Measures ability of the lungs to transfer gas from the air sacs into the blood stream using carbon monoxide
FEV1	Amount of air patient can forcefully exhale in the first second after taking a maximum inhalation
FEV1/FVC ratio	is the forced expiratory volume in one second expressed as a percentage of the forced vital capacity. The best valid FEV1 and best valid FVC are used to make this calculation even though they may come from separate efforts made during the same testing procedure. Generally speaking, in normal people, at least 72% of FVC is expired after one second. However, this changes with aging. The NSP medical criteria adjust the

required FEV1/FVC ratio for age.

FRC	Functional Residual Capacity - a measurement of air remaining in lung after normal exhalation - used to measure total lung capacity
FVC	Forced Vital Capacity - amount of air patient can forcefully exhale after taking a maximum inspiratory effort
fibrosis	Scarring
IC	Inspiratory Capacity
ILO	International Labor Organization - a reference to the standardized system for interpreting and grading x-rays for the pneumoconiosis group of diseases (of which asbestosis and silicosis are examples). This system was originally adopted by the International Labor Office in 1980. Asbestosis is characterized by the appearance of small, irregular opacifications on x-ray. There is a 12 point scale (0/0, 0/1, 1/1, etc.) identifying profusion. Pleural changes are also graded. The Agreement uses this system as a sliding scale to be used in determining impairment in conjunction with the PFTs
IVC	Inspiratory Vital Capacity
Impaired	derangement or loss of function
Nonmalignant	no cancer
PFT	(See pulmonary function test)

- Pleura** a thin covering over the outside of the lung
- "Pleural only" disease** means only the pleura has been diagnosed with a disease
- Pleural Plaque** a special kind of scar caused by asbestos on the lining of the lung
- Pleural/Pulmonary** refers to case where both the pleura and the lung are involved - in this case usually refers to asbestos involving both the lung and the lining around the lung
- Pneumoconiosis** nonmalignant disease of the lungs and pleura caused by mineral dust
- Predicted Values** Various studies have been reported in the medical literature on the normal results to be expected in the general population on TLC, FVC and FEV1/FVC and DLCO tests. According to the ATS, these predicted values are typically adjusted for sex, age, height, weight and race or ethnicity. Appendix A to the NSP agreements identifies the predicted values to be used for purposes of determining impairment under the NSP criteria. Generally speaking, if a person's individual result on a particular PFT value is within 20% of the predicted value, then the result is considered to be within the range of normal. Thus, subject to certain negotiated adjustments, the NSP medical criteria require an FVC of less than 80% of predicted or a TLC of less than 80% of predicted as a prerequisite to a determination of impairment. Qualification also is dependent on the presence of a normal age adjusted FEV1/FVC ratio.

Profusion the term used by radiologists to describe the number of abnormalities in a given area of the chest film. In terms of severity, profusion in the ILO system is graded as "0" for none, "1" for slight, "2" for moderate "3" for severe. Because of the inter-reader variability that is observed when only one grade is used, it is common for ILO readings to be expressed as two grades (e.g., 1/1 or 2/1). In this grading system, the first listed grade is the grade that the reader believes most likely to be correct. The second listed grade is a grade that the reader believes may possibly be correct, but that is less likely to be correct than the first listed grade. Thus, an ILO reading of 1/0 indicates that the reader believes that there is most likely a slight degree of interstitial fibrosis, but that the x-ray could in fact be normal. On the other hand, an ILO reading of 1/1 indicates the reader's firm conviction that there exists a slight degree of interstitial fibrosis.

Pulmonary refers to the lung

Pulmonary Function Test (PFT)

A series of tests performed which measure an individual's lung function. This is compared to a normal subject of similar age, height, sex and ethnicity(predicted values)

RV Residual Volume. Amount of air remaining in the lung after a forced maximal exhalation

TLC See Total Lung Capacity

Total lung capacity (TLC) equals the volume of air in the lungs after maximum inspiration and consists of the vital capacity (volume that can be

exhaled) plus the residual volume (volume that cannot be exhaled). It can also be measured by FRC and I.C. . . .

VA

Alveolar Volume

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